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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,028	06/23/2003	Harold Douglas Foster	HMT01/3619/US	1326

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	
MAIL DATE	**DELIVERY MODE**
10/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/600,028	FOSTER, HAROLD DOUGLAS	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/14/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the weight percents of the active compounds are not set forth in the body of the Specification. The Specification needs to be amended to include the claimed weight percents.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The nature of the invention:

The inventions is directed to preventing the development of human immunodeficiency virus (HIV) infection into acquired immunodeficiency syndrome (AIDS) by administering daily the combination of effective amounts of selenium, cysteine, tyrptophan and glutamine.

The state of the prior art and the predictability or lack thereof in the art:

The prior art does not disclose that AIDS can be prevented by administration of selenium, cysteine, tyrptophan and glutamine. As such, predictability in the art appears to be low with respect to prevention of AIDS after HIV infection.

The amount of direction or guidance present and the presence or absence of working examples:

The Specification refers to various unidentified studies which indicate there is selenium deficiency in individuals with HIV/AIDS, cysteine deficiency in HIV-infected patients, glutamine deficiency is a characteristic of AIDS and tryptophan deficiency is present in patients with advanced HIV-infection. Pages 7, 8. However, there is no evidence provided that administering these compounds will prevent the development of AIDS.

The breadth of the claims and the quantity of experimentation needed:

The claim is broad in that it claims prevention of progression to AIDS after HIV infection. Prevention of AIDS includes within the scope of the claim that an HIV infected patients which are treated with the claimed composition will never develop AIDS over their lifetime. As such, one of ordinary skill in the art would be required to do undue experimentation in order to show that the administration of selenium, cysteine, tryptophan and glutamine would prevent the progression to AIDS after HIV infection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The claimed invention is directed to composition containing selenium, cysteine, tryptophan and glutamine and reversing the symptoms of HIV infection by administering said composition.

Claims 1, 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shabert et al. in view of Werner et al. and Cope et al. (US Pat. 5,403,826).

Shabert et al. discloses the significant weight loss commonly occurs in patients with HIV infection (Page 860). It is disclosed that patients with HIV infection were given glutamine 40 g/d in combination with antioxidants, including selenium 280 micrograms/d and N-acetyl cysteine 2400.0 mg/d (Page 861). It is disclosed that the composition reversed wasting in the HIV patients (Page 863).

Werner et al. disclose that tryptophan levels are significantly reduced in HIV infected patients and that said decrease in tryptophan levels may contribute to the neurologic symptoms associated with HIV infection (Abstract).

Cope et al. disclose an nutritional product for HIV infected and AIDS patients which contains tryptophan (Columns 7, 8).

Shabert et al. disclose increased weight and reversal of wasting in HIV infected patients given a composition containing glutamine 40 g/d in combination with antioxidants, including selenium 280 micrograms/d and N-acetyl cysteine 2400.0 mg/d. The difference between Shabert et al. and the claimed invention is that Shabert et al. does not expressly disclose the addition of tryptophan. However, the prior art amply suggests the same as Werner et al. discloses that tryptophan levels are significantly reduced in HIV injected patients and that said deficiency may contribute to neurological symptoms and Cope et al. disclose the administration of tryptophan to

HIV infected and AIDS patients in a nutritional supplement. As such, one of ordinary skill in the art would expect that the addition of tryptophan would be effective in treating tryptophan deficiency in HIV infected and AIDS patients and reduce neurological symptoms which may be present as a result of the HIV infection.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
October 8, 2009

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616